



PHILIPS

MAR 15 2002

Philips Medical Systems

K020055

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name: Philips Medical Systems North America Company
Address: 22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003

Registration No.: 1217116

Contact Person: Lynn Harmer
Telephone No.: (425) 487-7312

Date Prepared: January 7, 2002

Device (Trade) Name: PHILIPS Integris Allura 9 system with FD Option

Classification Name: Angiographic x-ray system, Class II, 90 IZI
Solid x-ray Imager, Class II, 90 MBQ

Predicate Devices:

The Philips Integris Allura 9 System with FD Option is substantially equivalent to the Philips Integris H5000 system manufactured by Philips Medical Systems. The Integris H5000 received a 510(k) substantially equivalent determination in K984545 on February 25, 1999.

The FD option is also substantially equivalent to GE Medical Systems' solid state digital detector cleared by FDA on February 14, 2000, under 510(k) K993037.

Device Description:

The Philips Integris Allura 9 system with FD Option is an angiographic x-ray system with a solid state x-ray imaging device for cardiovascular diagnostic and interventional procedures. The monoplanar system can be configured as either a floor or ceiling suspended G-arm frontal stand. The x-ray detector is comprised of amorphous silicon with a cesium iodide scintillator. The system supports generating and recording x-ray diagnostic images using fluoroscopic and fluorographic techniques. X-ray images are

detected with a flat dynamic x-ray detector (FD) and are recorded on digital storage medium. The system offers the functionality to review and analyze the images. Digital images with corresponding patient and examination data may be archived on film (video or laser hardcopy) or on digital storage media.

Indications for Use:

The Philips Integris Allura 9 system with FD Option is intended for use in cardiac x-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placing, atherectomies) pacemaker implantations, and electrophysiology.

General Safety and Effectiveness:

The devices and their labeling will comply with the applicable requirements of 21 CFR, Subchapter J - Radiological Health, parts 1020.30, .31, and .32.

The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety, X-ray Equipment (UL 187 and UL 2601) and be classified by Underwriters Laboratories. The Integris Allura 9 system with FD Option will also comply with the ACR/NEMA DICOM digital imaging communication standard.

Conclusion:

The Phillips Integris Allura 9 system with FD Option does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Integris Allura 9 system with FD Option to be substantially equivalent with the predicate devices.



MAR 15 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K020055
Trade/Device Name: Philips Integris Allura 9
System with FD Option
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic
x-ray system
Regulatory Class: II
Product Code: 90 IZI and MQB
Dated: January 7, 2002
Received: January 8, 2002

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

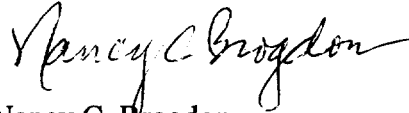
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020055

Device Name: Philips Integris Allura 9 system with FD Option

Indications for Use:

The Philips Integris Allura 9 system with FD Option is intended for use in cardiac imaging applications including diagnostic, interventional procedures (such as PTCA, stent placing, atherctomies,) pacemaker implantations, and electrophysiology (EP.)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020055

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐